REMARKS

Please reconsider this application in view of the above amendments and the following remarks.

- Claims 79-138 are pending.

None of the new claims consist of new matter. Support for the new claims can be found in the specification as originally filed. See the table below.

Claim	Support in specification as originally filed
Claim 79	Page 2, line 28—Page 3, line 18.
Claim 80	Page 2, line 28—Page 3, line 18.
Claim 81	Page 2, line 28—Page 3, line 18; and Page 7, line 8-26.
Claim 82	Page 2, line 28—Page 3, line 18.
Claim 83	Page 2, line 28—Page 3, line 18.
Claim 84	Page 2, line 28—Page 3, line 18; and Page 7, line 8-26.
Claim 85	See Claim 82.
Claim 86	See Claim 83.
Claim 87	See Claim 84.
Claim 88	See Claim 79.
Claim 89	See Claim 81.
Claim 90	See Claim 81.
Claim 91	See Claim 79-90.
Claim 92	See Claim 91 and Page 4.
Claim 93	See Claim 91 and Page 4.
Claim 94	See Claim 91 and Page 4.
Claim 95	See Claim 91 and Page 5.
Claim 96	See Claim 91 and Page 5.
Claim 97	
Claim 98	See Claim 91 and Page 3.
Claim 99	See Claim 98 and Page 4.

Claim 100	See Claim 98 and Page 4.
Claim 101	See Claim 98 and Page 4.
Claim 102	See Claim 98 and Page 4.
Claim 103	See Claim 91 and Page 4.
Claim 104	See Claim 91 and Page 4.
Claim 105	See Claim 91 and Page 4.
Claim 106	See Claim 103 and Page 4.
Claim 107	See Claim 106 and Page 5.
Claim 108	See Claim 106.
Claim 109	Claims 80, 81, 83, 84, or 85-90 and Page 3.
Claim 110	See Claim 109 and Page 9.
Claim 111	See Claim 109 and Page 9.
Claim 112	See Claim 109 and Page 9.
Claim 113	Claim 79, 81, 82, 84, 85-90
Claim 114	See Claim 113 and Page 9.
Claim 115	See Claim 113 and Page 9.
Claim 116	See Claim 113 and Page 9.
Claim 117	See Claim 110 and Claim 113.
Claim 118	See Claim 117 and Page 9.
Claim 119	See Claim 117 and Page 9.
Claim 120	See Claim 117 and Page 9.
Claim 121	See Claim 109 and Page 7.
Claim 122	See Claim 121 and Page 8.
Claim 123	See Claim 121 and Page 8.
Claim 124	See Claim 113 and Page 7.
Claim 125	See Claim 114 and Page 7.
Claim 126	See Claim 115 and Page 7.
Claim 127	See Claim 116 and Page 7.
Claim 128	See Claims 92, 93, 94, 95, 96, 99, 100, and 101.
Claim 129	
Claim 130	See Claim 79

Claim 131	See Claim 85.
Claim 132	See Claim 91
Claim 133	See Claim 92.
Claim 134	See Claim 93.
Claim 135	See Claim 94.
Claim 136	See Claim 95.
Claim 137	See Claim 96.
Claim 138	See Claim 97.

Claims 6, 56, 64 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian et al. (U.S. Patent No. 5,674,192).

Claims 6, 56, 64, and 69 have been canceled, but their subject matter is contained in the newly added claims. Therefore, Applicants discuss this anticipation rejection.

According to the Office Action, Sahatjian et al. disclose a medical kit comprising a coated stent deployed by a balloon catheter wherein the stent is coated with a therapeutic substance. Furthermore, it is disclosed that the sheath is made of polyurethane or TEFLON (fluorinated polymer). Sahatjian et al. teach that the sheath is for protecting the drug/coating and for inhibiting premature release of the drug. The protective sheath is for preventing the release of the drug before the sheath reaches the desired location in the body.

The Examiner has taken the position that Tg is inherently above storage temperature because the sheath's remaining a solid requires this. This is not correct. Tg is not the melting temperature of a polymer; simplistically, it is the point at which the polymer stops behaving in a crystalline manner and starts behaving in an elastomeric one. Common rubbers have Tg below room temperature, yet they remain solids.

With respect to an anticipatory rejection based in part on inherency, the law is clear. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be

established by probabilities or possibilities." MPEP § 2112 (quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teaching of the applied prior art." MPEP § 2112 (quoting *Ex Parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Therefore, one occurrence on record contrary to the examiner's inherency theory is enough to preclude a finding that a limitation is inherent in the prior art.

Sahatjian discloses that it uses Tecoflex™ polyurethanes. Appendix A provides a copy of *An investigation of the Fatigue Induced Failure Modes of Fiber/Elastomer Composites as Bearing Surfaces in Total Hip Joint Prosthesis*, published by the National Textile Center in its 1997 Annual report. This article shows the measurement of some Tecoflex™ polyurethanes. Reference to Table 1 of the Appendix shows that a medical grade Tecoflex has a Tg of as low as -69.10. Moreover, at least two grades have static (low frequency) glass transition temperatures of below room temperature.

Because not all of Sahatijan's polyurethanes must have a glass transition temperature above a storage temperature, anticipation based on inherency is not proper.

Please remove this rejection of the subject matter of Claims 6, 56, 64, and 69.

Claims 7-8, 57-58, 65, 70 are rejected under 35 U.S.C. 103(a) as obvious over Sahatjian et al. (U.S. Patent No. 5,674,192).

Claims 7-8, 57-58, 65, 70 have been canceled, but their subject matter is contained in the newly added claims. Therefore, Applicants discuss this obviousness rejection.

The Examiner's reasoning for finding these claims obvious appears to be that in the absence of evidence to the contrary (to be provided by Applicant) prima facie obviousness is assumed. The Examiner has completely ignored the proper procedure of first demonstrating a prima facie case of obviousness and then analyzing obviousness

based on the Graham criteria. Since it is incumbent on Applicants under the Administrative Procedure Act to provide a record when the Agency has failed in that duty, we set out the following discussion.

The Office Action identifies the following as missing from the disclosure of Sahatjian: "[It] does not disclose the non-polar soft segment to be hydrocarbons or silicones or fluorosilicones or mixtures thereof". The next step in making out prima facie obviousness is to point to evidence why one of ordinary skill in the art would modify Sahatjian by changing its non-polar soft segments into hydrocarbons or silicones or fluorosilicones, or mixtures thereof. The Office Action says that it is known in the art to so modify non-polar segments to provide flexibility and bendability.

To the extent that the Examiner intends to take official notice of that purported knowledge of a skilled artisan, Applicants note MPEP § 2144.03. MPEP § 2144.03 states that "the rationale for supporting an obviousness rejection may be based on common knowledge in the art or 'well-known' prior art" and the "examiner may take official notice of facts outside of the record which are ***capable of instant and unquestionable demonstration*** as being 'well-known' in the art." If an applicant traverses such an assertion, the Examiner is required to cite a reference in support of the Examiner's position.

Applicants traverse that assertion and ask for such a reference. Specifically, Applicants request a reference that shows that one of ordinary skill in the art would have expected that modifying the soft blocks of the Sahatjian polyurethanes would provide flexibility and bendability to those polyurethanes. Applicants point out that some of Sahatijan's polyurethanes are elastomeric. Therefore, a proper reference would show that one of ordinary skill in the art would have reasonably expected that modifying the soft blocks of those particular elastomers into hydrocarbons, silicones, fluorosilicones or mixtures thereof would improve rather than impair the materials' flexibility and bendability. If such a reference were to exist, it would partially address the likelihood-of-success prong of the obviousness prima facie case.

In addition to the success prong, Applicants traverse the above assertion and ask for evidence that addresses the motivation prong of the prima facie case. The Examiner must provide evidence showing why one of ordinary skill in the art would have been motivated to make the modifications the Examiner identifies as obvious. Applicants note that the Examiner need not identify a motivation that is the same as Applicants' motivation. Therefore, this discussion centers on the motivation posited by the Examiner in the current office action. To be sufficient, a reference would at least require some evidence that those of ordinary skill in the art recognized that Sahatijan's polymers were unsuitable because of the lack of bendability or flexibility. In fact, Sahatjian used its polymers to successfully make catheters for insertion into the body. The Examiner has not provided evidence why a skilled artisan, when presented with polymers flexible and bendable enough for use in catheters, would desire to increase the flexibility and bendability of those polymers before employing them in the medical arts. If there is no reason to make a modification, it is not obvious to make it.

The Examiner may not assume obviousness. Instead, the Examiner must provide evidence why an ordinary skilled artisan would be motivated to change the invention of the identified reference into Applicants' invention and why that artisan would expect the change to be successful. Since that evidence is not of record, Applicants ask the Examiner to remove this rejection under §103(a). Alternatively, Applicants traverse the Office Action's reliance on the Examiner's assertions of what those of ordinary skill know and request documentary evidence of that knowledge, as is required by MPEP § 2144.03.

Please remove this rejection of the subject matter of Claims 7-8, 57-58, 65, and 70.

All claims are in a condition for allowance, please issue a Notice of Allowability so stating. If I can be of any help, please contact me.

Respectfully submitted,

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Date: December 18, 2003

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APPENDIX A

C94-2

An Investigation of the Fatigue Induced Failure Modes of Fiber/Elastomer Composites as Bearing Surfaces in Total Hip Joint Prosthesis

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M. LaBerge, Ph.D., Associate Professor of Bioengineering

Goal Statement

This research represents a fundamental study of the failure mechanisms observed in fiber reinforced elastomeric bearing surfaces. The goal of this research is to develop a better fundamental understanding of all complex modes of failure in bearing surfaces which can then be used to design new materials with sufficient longevity for use in total joint replacements or other bearing applications.

Abstract

It is proposed to use elastomeric composites as artificial joint bearing surfaces to increase their fluid film lubrication and therefore reduce the number of failures which have been attributed to wear mechanisms. The fluid generated between the surfaces supports part of the load and prevents direct contact of the bearing surfaces. In order to obtain optimum elastohydrodynamic lubrication, elastomeric materials are selected based on their static mechanical properties such as modulus of elasticity. However, the observed permanent deformation and failure of model elastomeric composites has been associated with debonding between fibers and matrix. It is hypothesized that the operating conditions such as frequency (velocity) and temperature at the contact between the elastomeric composite and the reciprocating counter part may contribute significantly to the failure of the elastomer. The mechanical properties of elastomers as of other polymers are highly dependent on strain rate, frequency, and temperature. Polyurethane thermoplastic elastomers of three different hardnesses (85A, 93A, 100A) were characterized with dynamic mechanical thermal analysis. The coefficient of friction between these materials and metal was measured using reciprocating motion. Data showed that the lubrication mode of a metal-elastomer contact in tribological conditions observed in artificial joints is highly dependent on temperature and frequency. In this respect, dynamic mechanical analysis can be used in the selection of an optimal elastomeric material for reciprocating bearing conditions.

Introduction

Low modulus elastomeric coatings were proposed and investigated by several authors as a method to improve the tribological performance of bearings (Unsworth et al., 1987; Dowson et al., 1991). By deforming under pressure, elastomeric layers enhance lubrication by the formation of a fluid film through elastohydrodynamic and micro-elastohydrodynamic lubrication (Dowson and Jin, 1986). This occurs when the asperities of these materials flatten due to local pressure perturbations. However, when the fluid film breaks down, adhesive friction increases in presence of smoother elastomeric materials (Fuller and Tabor, 1975). Lower modulus materials provide more effective micro-elastohydrodynamic lubrication but fail due to an increase in shear strain. Dowson et al. (1991) suggested that the elastic modulus should not be lower than necessary to provide effective micro-elastohydrodynamic lubrication. However, these authors did not address the fundamental effect of temperature (heat) as experienced in tribological contacts and operating conditions on the dynamic mechanical properties of polymers and elastomers and therefore, on the lubrication mechanism and subsequent failure of the elastomers.

Research on the use of LME as bearing surfaces done thus far has focused on the evaluating experimentally and theoretically the tribological behavior of the elastomer layer. However, a more in-depth understanding of the material properties of elastomers is necessary to predict the behavior of these bearings in the complex environment of the body. Two variables which can have a profound effect on the mechanical properties, such as the modulus of elastomers, and have not been considered to date in the available literature are temperature and frequency. The objective of this research was to:

> *" characterize the effects of temperature and frequency on the modulus of a selected set of elastomers, and to relate these parameters to both, theoretical and experimental tribological results. "*

The long term goal of this research is to develop a better fundamental understanding of all of the complex modes of failure in bearing surfaces which can then be used to design new materials with sufficient longevity for use in a total

joint replacement or industrial bearings. The following specific aims were addressed this year in order to reach this goal:

- to characterize the thermal and thermo-mechanical material properties of a selected set of polyurethane elastomers,
- to evaluate the theoretical tribological properties of the polyurethane bearing surface based on the results of the materials characterization, and
- to compare the experimental results of the tribological characterization of the elastomeric layers as a function of frequency and temperature with the theoretical tribological evaluation.

Materials & Methods

In order to reach the above goals, the project was divided into four phases: 1) fabrication of testing samples, 2) dynamic mechanical thermal analysis of the test samples, and 3) tribological analysis of the contact elastomer-metal as a function of frequency and temperature.

1. Sample Fabrication

Three grades of a low modulus medical grade aliphatic polyether-based polyurethane elastomer (Tecoflex ® SG 85A, 93A, 100A by Thermedics Inc., Woburn, MA) were used to as test materials. Tecoflex® resins are reaction products synthesized from methylene bis(cyclohexyl) diisocyanate [HMDI], poly(tetramethylene ether glycol) [PTMEG], and 1,4 butane diol chain extender. Based on our previous results showing that solution casting did not allow a uniform thickness layer greater than 1 mm to be obtained, the test samples were compression molded. Prior to fabrication, the hydroscopic pellets were dried in a vacuum oven at approximately 75°C for at least three hours to remove any water content and stored in a desiccator until the time of fabrication. The pellets were placed in a 2.38 mm thick polytetrafluoroethylene mold (8.89 cm X 11.43 cm) with polytetrafluoroethylene release ply (Teflon@/ Wrightlon 5900, Airtech International, Carson, CA) placed between the elastomer pellets and the metal plates to prevent the elastomer from adhering to the plates. The pellets were then heated in a Carver laboratory press (Model C, Fred S. Carver Inc., Wabash, IN) for 25 minutes, up to 350°F, under a constant pressure of 3000 lbs and cooled down to room temperature using the cooling system on the press.

Samples were then sectioned for the dynamic mechanical thermal analysis (DMTA) and tribological analysis. Thermocouples (0.005 inch diameter Type T, Omega, Inc.) were embedded into the elastomer (1 mm from surface) in several positions to measure the frictional heat generated as a function of time.

2. Material Property Characterization

Dynamic mechanical thermal analysis (DMTA) is being used in this project to characterize the thermo-mechanical properties of the elastomer, such as the glass transition temperature, the loss modulus, and storage modulus. These material parameters are used in studying the fatigue failure of the Tecoflex® utilizing the principle of time-temperature super positioning.

The time-temperature superposition principle can be very useful in studying polymers. It allows for the extrapolation of the transition behavior to frequencies beyond the instruments measurement range and separates the effects of time and temperature. To achieve this superposition, DMTA curves obtained at various frequencies during pseudo-isothermal scans are shifted to some arbitrary reference temperature by a horizontal shift factor, a_T, to produce a composite "master" curve covering a wider frequency range.

The DMTA experiments (Seiko DMS 210) were run on the various solution grades of the Tecoflex® including 80A, 85A, 93A, 100A, and 60D where the A and the D designate the Shore hardness scale. The experiments were run from -100°C to 100°C at 0.05°C/min. using eight frequencies ranging from 0.02 to 10 Hz. Data obtained with DMTA were used to theoretically predict the lubrication modes as will be described below.

3. Tribological Analysis

The effect of reciprocating motion and friction between mirror polished cylindrical cobalt-chrome alloy (ASTM F-75) bearings and flat elastomeric sheets were evaluated under mixed and fluid film lubrication conditions using a reciprocating pin-on-plate friction table. This 3-station pin-on-plate friction table simulates the line contact as in a typical artificial knee joint. Strain gauges are used to determine the friction force. Friction tests were conducted at various operating speeds simulating normal joint motion to evaluate the effect of operating frequency on the lubrication mode. A multi-channel data acquisition system was designed using LabView™ (National Instruments, TX) to measure T below the line contact and friction as a function of time. A tribological model previously

developed by the investigators to study the effect of material stiffness and lubricant viscosity on artificial joint lubrication was used to generate calibration curves (friction versus Sommerfeld number). Tests were conducted at room temperature (RT), 37°C (body temperature), and 45°C (temperature of an inflamed joint often observed after joint replacement.

The low modulus materials were secured to the reciprocating table and served as the lower bearing surface. The total travel distance was 124 mm/cycle or 62 mm in each direction. The velocity of the platform was controlled by a speed dial adjacent to the system and was monitored by a linear variable displacement transducer (Model 3000 HR, S/N 320, Lucas Schaevitz, Pennsauken, NJ).). Tests were conducted at 1Hz and 2Hz simulating slow and fast walking patterns under a contact stress of 2 MPa (within physiological stresses observed in human joints). 20 ml of lubricant was placed on the bearing surface. Glycerin (Humco Laboratory, Texarkana, TX) was chosen as lubricant because it is a Newtonian fluid and therefore independent of the shear rate. Glycerin was diluted with distilled water to obtain an 86% solution. The concentration chosen for this study corresponded to the apparent viscosity of degenerated synovial fluid at low shear rates (- 1 s^{-1}) which was 100 cP, as given by Davies and Palfrey (1969). According to Miner and Dalton (1953), an 86% glycerin solution has an absolute viscosity of 100 cP at 25°C. The upper bearing surface was then lowered on top of the lower bearing surface and the machine was turned on. Resistance to sliding was measured by the force transducers. The voltage output from the transducers was amplified and used to determine the force required to hold the jig in place while the reciprocating plate moved. By use of Amonton's law, the coefficient of friction could be determined. All tests were conducted in an environmental chamber. A total of six tests were conducted for each set of experimental conditions (frequency and temperature) for each grade for up to 50,000 cycles.

A statistical analysis was performed using a general linear model to compare the effect of frequency and grade on dynamic mechanical properties as well as the effect of experimental conditions on optimization of lubrication modes.

Results and Discussion

Material Characterization

The DMTA curves obtained for the different grades of Tecoflex® illustrate the effects of both the soft and the hard segments in its composition. The value of tan 6, the glass transition temperature (Tg), and the loss and storage modulus were compared as a function of grade, frequency, and temperature. The purpose of evaluating Tg was to understand the effects of frequency on the glass transition temperature and characterize the difference in the material behavior from both a thermo-mechanical and tribological view both above and below this transition.

The soft 85A grade of elastomer exhibited two primary transitions on the tan δ curve. The first peak on the 1 Hz DMTA curve occurred at approximately, -57°C and the second, more prominent peak on the tan δ curve was observed at approximately +28°C. This two peak behavior is representative of the two glass transition temperatures of both the hard and the soft segments and has been seen in other two phase microstructure polymer systems (Encyclopedia of Polymer Science, 1989). The -57°C representing the transition of the soft polyether segments and the +28°C that of the Tg for the hard urethane segments. An additional indication of transitions at both of the temperatures is the change in slope of both the storage and loss modulus curves. The 93A which was the intermediate polyurethane hardness grade evaluated demonstrated only one prominent peak above room temperature which would represent the glass transition temperature of the hard urethane segments. However, both the loss and storage modulus as well as the tan δ curves indicate an additional transition at around -50°C, which occurs close to the glass transition temperature of the soft segments. The 100A grade of Tecoflex® polyurethane, the hardest grade evaluated, also showed its most distinct peak at approximately 50°C which again corresponds to the hard segment transition. A slight change in slope of both the storage and loss modulus curves at around -50°C was also indicative of a transition in soft segments of the polyurethane polymer system. The DMTA's from both the 93A and the 100A suggest a stronger influence of the hard segments in comparison to the 85A because of the presence of one prominent transition instead of the two. However, the soft segments are present in both elastomers and their interaction with the hard domains will effect any of the elastomer's material properties. At the lower content of the hard segments present in the elastomer, as with the 85A grade, the structure of the elastomer can be described as disordered hard segments distributed within a matrix of the soft polyether segments. As the amount of hard segments increases, in the case of the 93A and 100A elastomeric grades, the more hard segments can aggregate and organize into lamellar hard microdomains. The transition between the two occurs at a critical segment lengths as defined by Koberstein et al. (1992) and Lelah et al. (1986).

The mean Tg results as a function of frequency obtained from the DMTA experiments are summarized in Table 1. The most profound effect of frequency was on the 85A grade of Tecoflex® elastomer at both transition peaks. A statistical analysis of the 85A data which compared the mean recorded Tg values using ANOVA (α=0.05) was done and the glass transition temperature at all eight of the frequencies were statistically significantly different from each other at both the hard and soft segment glass transition peaks. For both the 93A and 100A elastomer grades, the effect of frequency on the Tg was not as clearly defined between each pair of frequencies as with the 85A. Overall, only the glass transition temperatures at both 0.1 and 0.02 Hz for each of these two grades of polyurethane were determined to be statistically significantly different from all of the other frequencies and each other. The standard deviations of the Tg values obtained at the higher frequencies for the 93A and 100A elastomer grades overlapped each other.

Table 1 Mean Values and Standard Deviation for the Glass Transition Temperature ("C)

Grade	10 Hz	5 Hz	2 Hz	1 Hz	0.5 Hz	0.2 Hz	0.1 Hz	0.02 Hz
85A Mean	-45.68	-49.76	-53.68	-57.52	-59.90	-63.68	-67.00	-69.10
Std Dev.	4.13	6.88	5.51	4.40	4.45	3.88	3.36	4.62
85A Mean	53.54	47.10	37.00	28.44	22.92	15.46	8.06	1.94
Std Dev.	9.84	11.26	13.61	14.03	14.16	15.46	3.65	1.90
93A	41.98	37.40	32.22	29.12	25.78	22.42	18.84	14.72
Std Dev.	3.91	3.14	3.01	1.96	2.98	2.66	4.34	1.21
100A	53.26	50.82	47.36	44.92	42.52	40.14	38.56	32.68
Std Dev.	0.92	0.95	1.53	1.53	1.49	2.83	2.46	4.07

Dynamic mechanical analysis results showed that at the test frequencies used to perform the frictional analysis, the elastomeric material is significantly behaving differently. An increase in modulus is observed for the three grades studied, 85A, 93A, and 100A, as a function of frequency increase (Figure 1) and temperature observed in the body (37°C is body temperature and 45°C is reported temperature between articulating orthopaedic surfaces (metal-polyethylene) (Figure 2). These results indicate that the use of a single value as representative of the mechanical properties of the elastomer in the prediction of lubrication mechanisms for different test frequencies is not appropriate since the material behaves differently as a function of this parameter.

For each grade of elastomer studied, the modulus decreased as a function of temperature as the elastomer began to soften, except for the case of the 85A at 45°C (Table 2). This apparent discrepancy of the 85A grade at 45°C can be attribute to the large standard deviation. One of the five modulus measurements was double the modulus of the others. Since no specific reason could be identified why this test should be disregarded, this result was kept in the data for analysis purposes. Without this modulus value of 14.17 MPa, the 85A at 45°C would average 7.74 MPa instead of 9.17 MPa. The statistical analysis of the 85A indentation modulus data indicated that all of the calculated mean modulus values as a function of temperature were statistically significantly similar to each other when compared using ANOVA (a = 0.05). Similar results were obtained from the statistical analysis of the other two grades.

Table 2. Comparison of TMA as a function of temperature and elastomeric grade.

Tecoflex® Sample	Modulus @ 25°C (MPa)	Modulus @ 37°C (MPa)	Modulus @ 45°C (MPa)
85A	7.80 ± 0.88	7.36 ± 1.12	9.17 ± 3.32
93A	16.03 ± 1.85	14.52 ± 3.11	12.75 ± 1.88
100A	12.78 ± 2.95	10.71 ± 2.24	8.12 ± 2.02

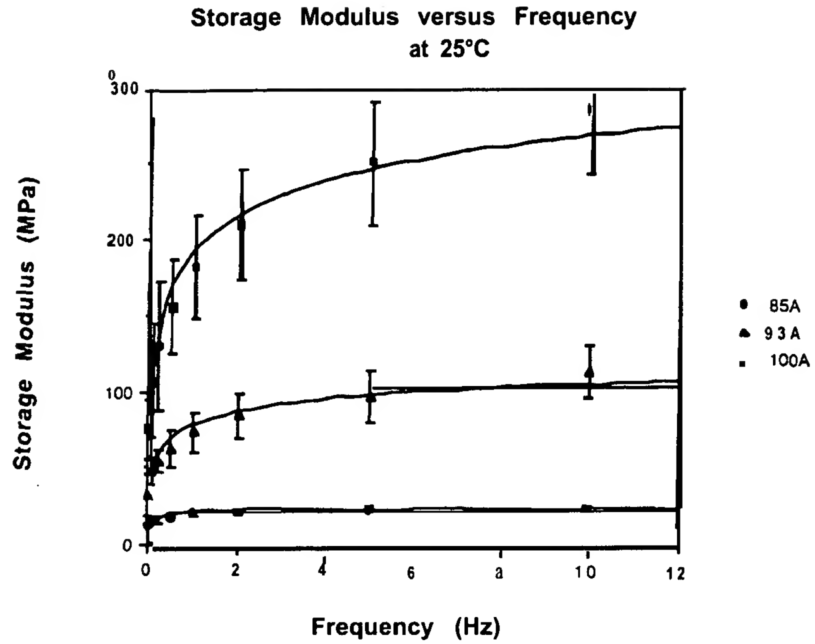

Figure 1. Effect of the frequency on the storage modulus of different grades (hardnesses) of Tecoflex.

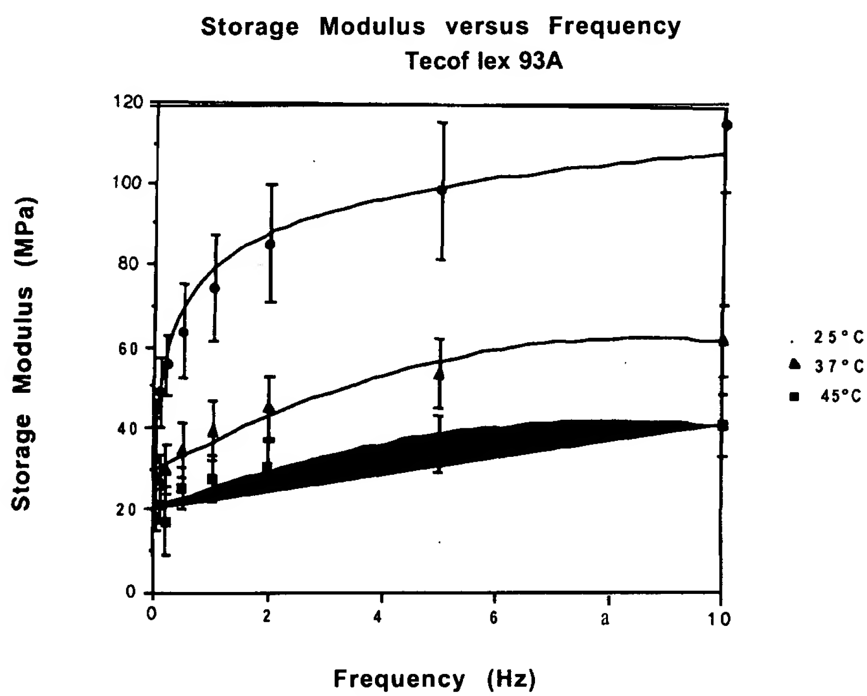

Figure 2. Effect of frequency on the storage modulus of Tecoflex SG93A for different operating temperatures.

Elastomers are profoundly influenced by both temperature and frequency as demonstrated in this material characterization section. The most profound influence of these parameters occur in the stiffer grades of elastomer as the hard segment content is increased. In the literature, however, the importance of these visco-elastic properties have often not been considered in the evaluation, such as in the case of the polyurethane elastomers being considered for cushion bearing joint replacements. To date, in the available literature, all of the tribological testing reported was done at room temperature. The body temperature is approximately 12°C higher than room temperature and the mechanical properties of an elastomer have been shown in this analysis to change significantly as a function of temperature over this range. As a result, this author believes the tribological properties of cushion bearing joints will be profoundly influenced by the combination of temperatures and frequency.

Tribological Analysis

The reason for analyzing the lubrication regimes which were present experimentally and would be predicted theoretically was to gain an understanding of how much interaction existed between the bearing surfaces. The lubrication regime is based on the calculation of the lambda ratio (h) which is based on both the central film thickness as well as the surface roughness. When the λ is less than 1, the boundary lubrication regime dominates and the extent of surface contact is high. For a λ of 3 and higher, the elastohydrodynamic lubrication regime theory predicts no contact of the bearing surfaces will occur. In the mixed lubrication regime, $3 \leq \lambda \leq 1$, intermittent surface interaction does occur.

The contact stress analysis, necessary to generate the λ ratio, was done for each of the elastomer grades as a function of frequency and temperature. The effects of frequency and temperature have been shown to profoundly impact the resulting stress values for all of the grades of elastomer. The basic trend is as temperature increases, the stress is reduced. The reduced stress is the direct result of the lower modulus values as the material is able to deform.

The 93A grade of elastomer was selected as the candidate material for tribological analysis because it was the intermediate grade evaluated in the material characterization portion of this research. The friction testing was done at room temperature (≈22°C), 37°C, and 45°C and at the frequencies of 1 and 2 Hz. The coefficient of friction in general decreased as a function of time for all of the experimental conditions with 100 cycles being typically the highest friction and 5000 cycles being the lowest. Statistical analysis using ANOVA (α=0.05) was done initially to study the effects of the number of cycles. The only statistical differences observed in the friction values as a function of time occurred between 100 and 5000 cycles. Therefore, for the statistical analysis of the effects of frequency and temperature, comparisons were only made with the 100 and 5000 cycles friction data. Overall, the experimental friction values measured during the course of the testing ranged from 0.03 to 0.1 depending on the frequency and temperature of the testing. This trend has also been observed by other authors and is the result of theory not including EHL effects (Auger et al., 1990; Auger et al., 1993; Caravia et al., 1993; Graham, 1994). The reason for this difference in the theory is that it is strictly based on the ratio of viscosity, velocity, contact area, applied load, and central film thickness. In these cases, the only variables which are changing are the velocity, contact area, and the central film thickness. The equation does not consider EHL or micro-EHL effects.

The minimum fluid film thickness and the lambda ratio results for the experimental portion of the tribological characterization are presented in Table 3. Based on the results for the lambda ratio, the lubrication mode for the experimental tribo-system was identified. The modulus values used for the calculations were from the DMTA storage modulus results for the 93A grade of elastomer at the frequencies 1 and 2 Hz. The basic trend observed was the higher the storage modulus, which corresponded with the higher frequency measured by the DMTA, the lower the minimum fluid film thickness and the lambda ratio. This phenomena can be explained by understanding the relationship between the modulus and the resulting fluid film thickness generated. The higher modulus elastomers, as in the case of the storage modulus values at the higher frequencies, are stiffer by nature and are not able to deform as much under the pressure wedge generated in the lubricant as a function of velocity. As a result, thinner lubricating films are created which in turn, depending on the surface roughness, have lower λ ratio values. With the rise in temperature, however, a decrease in the film thickness and the lambda ratio was observed, opposite to the expected increase in both the minimum fluid film thickness and the λ ratio. The reason for this decrease was attributed to the decrease in the viscosity of the glycerin. At 25°C, the viscosity of the glycerin is 945 cP which decreases dramatically at 37°C to 500 cP and at 45°C to 300 cP. The decrease is not as dramatic as if the stiffer 25°C DMTA storage modulus of the 93A elastomer were to be used in the calculations for the fluid film thickness and the lambda ratio at both 37°C and 45°C. Based on the equation for calculating the minimum fluid film thickness in which the modulus is in the denominator, the lower storage modulus values measured by the DMTA

compensate for the decrease in the viscosity of the lubricant with temperature and allowed for greater minimum fluid film thickness and a higher λ ratio (Figures 3, 4, and 5).

Table 3. Experimental Lubrication Analysis Results

Velocity	Frequency	Minimum Film Thickness			Lambda Ratio		
(mm/sec)	(Hz)	25°C	37°C	45°C	25°C	37°C	45°C
10	2	1.34	1.17	1.00	1.01	0.89	0.76
10	1	1.41	1.23	1.05	1.07	0.94	0.79
30	2	2.59	2.27	1.93	1.96	1.72	1.46
30	1	2.73	2.39	2.02	2.07	1.81	1.53
60*	2	3.92	3.43	2.93	2.97	2.60	2.22

* The peak velocity for the 2 Hz experimental evaluation.

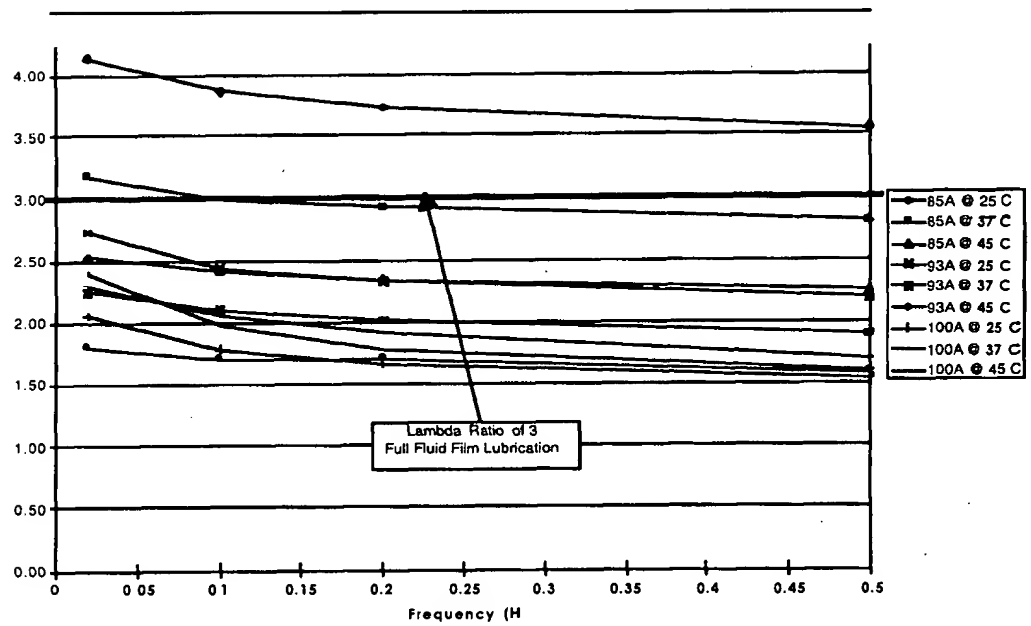

Figure 3. Lambda ratio based on the DMTA modulus results as a function of frequency at 30 mm/s at the lower frequencies.

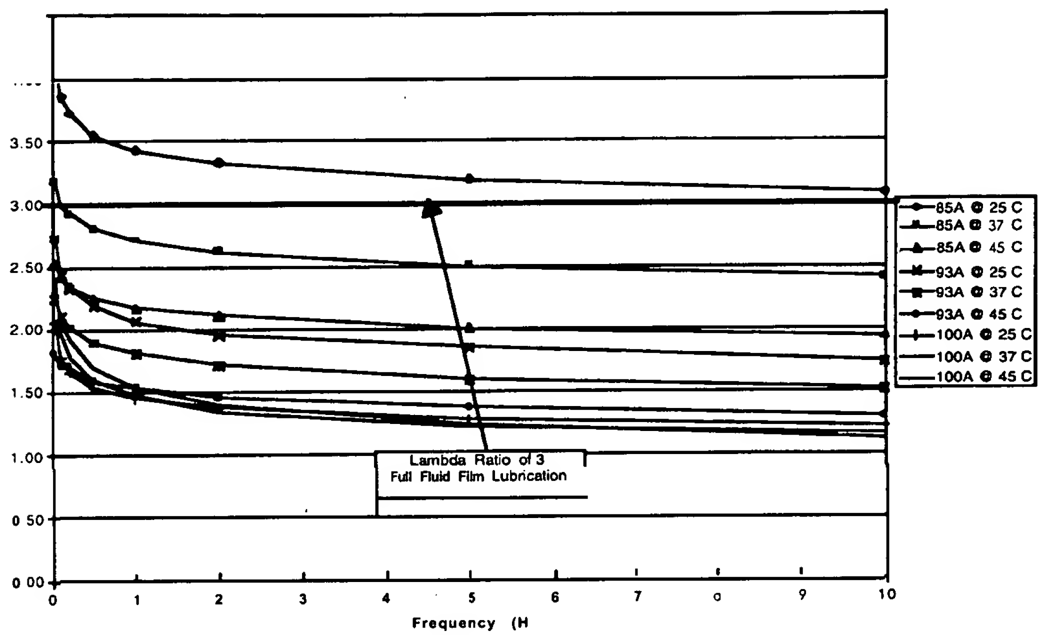

Figure 4. Lambda ratio based on the DMTA modulus results as a function of frequency at 30 mm/s.

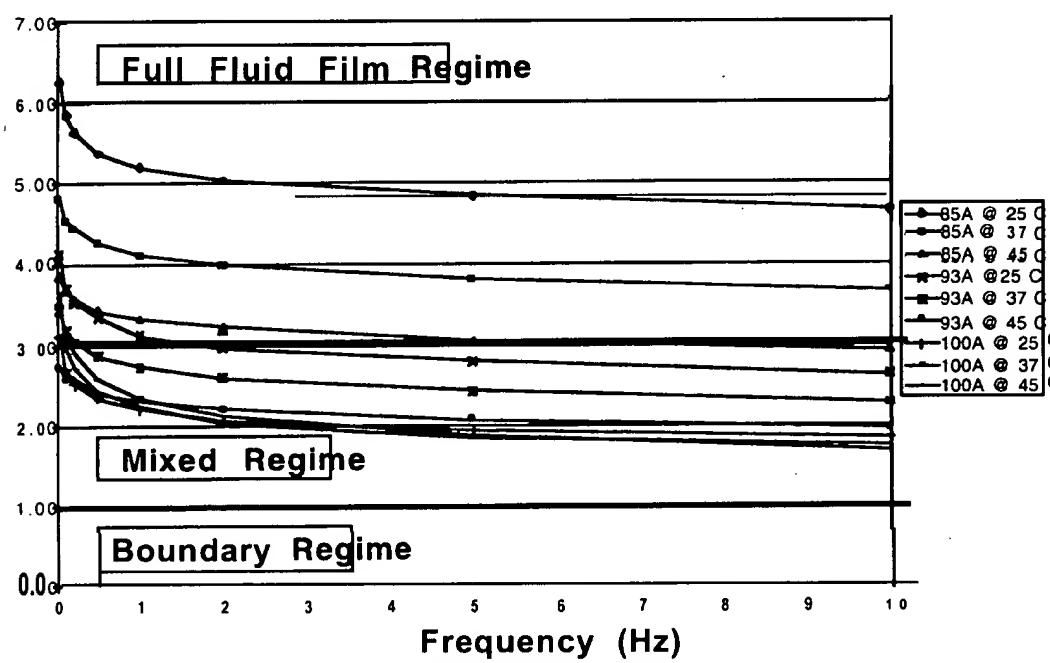

Figure 5. Lambda ratio based on the DMTA modulus results as a function of frequency at 60 mm/s

Results obtained with the tribological study suggest that for the grade SG93A, different lubrication mechanisms are observed with different environmental temperatures. Heat may have contributed to reduce the viscosity of the glycerin solution. For a 2.5" C increase, the viscosity of the glycerin solution would decrease by almost 10 cP

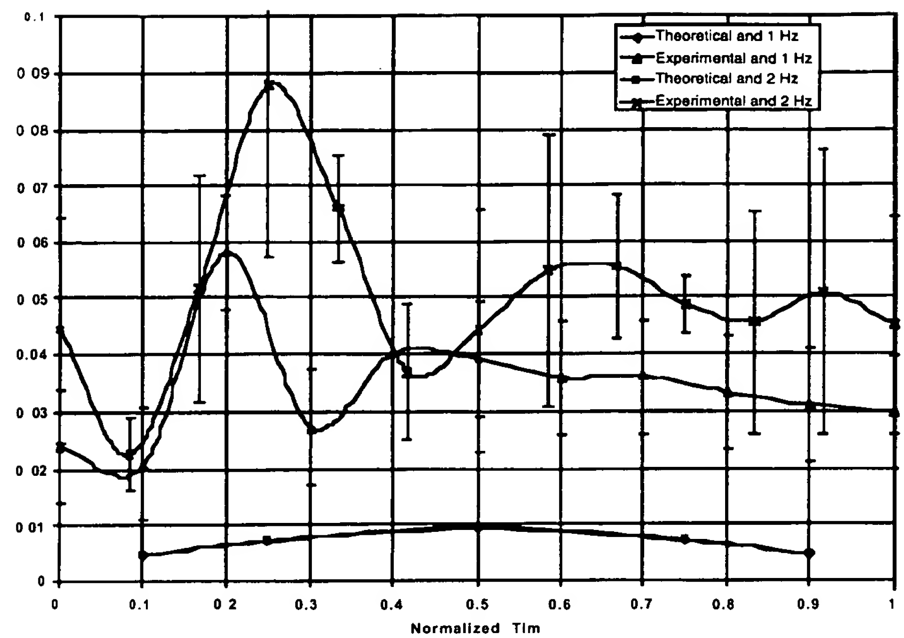

Figure 6. Theoretical and experimental coefficients of friction against normalized time at 37°C.

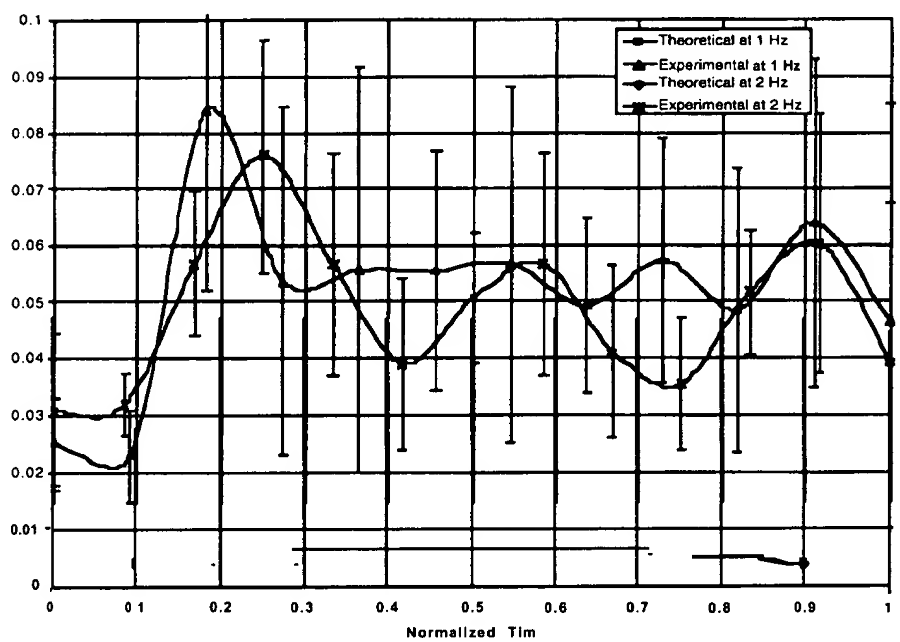

Figure 7. Theoretical and experimental coefficients of friction against normalized time at 45°C.

(Miner and Dalton, 1953). Therefore, temperature influences severely the viscosity of the lubricant and may have contributed to an increase in friction at higher temperature as shown with the theoretical curve (Figure 5). However, experimental results showed that overall fluid film lubrication is better observed at 37°C and 45°C than at room temperature. In these cases the experimental friction values exceeded the theoretical friction values (Figures 6 and 7).

Conclusions

Experimental studies conducted by Auger et al. (1992) and Caravia et al. (1993) have shown that the frictional behavior of elastomeric coatings was highly dependent on the modulus of elasticity of the coating at a low velocity (8 mm/sec). For the contact elastomer-metal, increasing the stiffness of elastomeric coatings increases the start up friction of the contact for boundary lubrication conditions (Caravia et al., 1993). Dowson et al. (1991) suggested that the elastic modulus should not be lower than necessary to provide effective micro-elastohydrodynamic lubrication. A further reduction in elastic modulus would therefore increase the shear strains above acceptable limits. The results obtained in this study also emphasize that the elastomer properties will be different at different frequencies which will contribute to possible failure of the material due to fatigue. Also, LME materials deform more easily thus enhancing micro-elastohydrodynamic lubrication, however, as stated previously the lower modulus layer cannot withstand the stresses and strains experienced under physiological conditions.

Acknowledgments

The authors thank the National Textile Center for their financial support, Tara E. McGovern for conducting the experiments as part of her master's thesis in Materials Science and Engineering at Clemson University.

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